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**Genetic Privacy, Discrimination and Research in Washington State:
Findings, Conclusions and Recommendations of the
Washington State Board of Health Genetics Task Force**

The Subcommittees

The GTF organized into the following four subcommittees in order to clearly delineate some of the different circumstances in which an individual's genetic information may be obtained and used:

1) The use of genetic information for health care including:
    a) the diagnosis of symptomatic patients;
    b) reproductive decision-making; and
    c) predictive genetic testing for low penetrant genetic disorders
2) State mandated DNA collection and testing including:
    a) newborn screening; and
    b) criminal DNA databases;
3) The use of genetic information for research purposes; and
4) The use of genetic information for social purposes such as health, life and disability insurance and employment.

<u>Subcommittee One: The use of genetic information for health care including: a) the diagnosis of symptomatic patients; b) reproductive decision-making; and c) predictive genetic testing for low penetrant genetic disorders</u>

Subcommittee One analyzed the information presented to the GTF from the perspective of the health and medical care system. The use of the term "genetic test" in the context of this

report includes the analysis of DNA, RNA, chromosomes, proteins, or other gene products to detect disease-related genotypes, mutations or karyotypes for clinical purposes or phenotype prediction.

Genetic information is used in a variety of ways within the health and medical care system. For example, physicians use it for the medical diagnosis of symptomatic patients. This generally occurs through either chromosome or DNA analysis conducted in licensed medical laboratories. Physicians may request DNA analysis of blood samples from children with mental retardation who are suspected of having Fragile X syndrome, from males with symptoms of Duchenne muscular dystrophy, from persons with a clotting disorder, or from adults with muscle and neurologic changes suggestive of a genetic condition. The introduction of DNA testing has simplified the medical diagnosis of these and many other conditions that in the past may have involved anesthesia, muscle biopsies, or expensive and laborious testing by other means.

Physicians and counselors also use genetic information to assist people with reproductive decisions. DNA technology is a very powerful tool in reproductive medicine. In general, the technology is used in two ways: 1) identification of asymptomatic pregnant couples at risk for having a newborn with a severe genetic disease; and 2) utilization of DNA technology in subsequent pregnancies in families that have previously given birth to a child with a genetic disorder. Both situations offer parents and health care providers the opportunity to prevent or prepare for the birth of a child affected by a genetic disorder.

A third way that health care providers use genetic information is for the predictive identification of genetic risk factors associated with late-onset diseases. In certain instances, DNA testing can identify genetic predisposition to a disease prior to the onset of clinical symptoms. This type of testing may be used in three different situations. Young children at high

risk for developing a serious disorder for which intervention may be available can be tested for a genetic predisposition to the disorder before symptoms arise. Predictive genetic testing may be offered to infants who have a sibling with cystic fibrosis, male children in families with Duchenne muscular dystrophy, or children born into a family at high risk for a genetic disease for which therapy is available.

The second category of predictive genetic testing is more complicated. A number of disorders exist in which clinical symptoms do not present until adulthood. DNA technology has the potential to identify individuals at risk for some of these conditions at any age prior to the onset of symptoms. Genetic testing can predict some of these disorders with a finite probability prior to the onset of symptoms if an individual carries a particular form of a gene associated with the disorder. Examples include the predilection for breast cancer in individuals who carry an abnormality of the BRCA1 or BRCA2 genes, or the predilection for neurological degeneration around the age of 40 in individuals with an abnormality of the Huntington disease gene. In the case of a woman with a strong family history of breast cancer, it may be appropriate to screen that woman by DNA testing to determine her genetic risk of developing breast cancer. Screening allows for early detection or prevention of breast cancer in a woman with mutations in BRCA1 or BRCA2. In the case of Huntington disease, an autosomal dominant condition, children of an affected individual are at 50 percent risk for developing the condition in adulthood, but there exist no medical strategies for treatment or cure. In this case, DNA testing may be appropriate for medical information and for personal decision-making on lifestyle changes.

A third use of predictive genetic testing is the testing of children under 18 years of age for medical conditions that may present in adulthood; for example testing for susceptibility to breast cancer or Huntington disease. Many health care providers consider it unethical to test

children for adult onset disorders prior to the age when they can give informed consent. This opinion applies to children born into families who are at increased risk for adult onset diseases or children being placed for adoption with no known prior risk factors.

Subcommittee Two: State mandated DNA collection and testing including: a) newborn screening; and b) criminal DNA databases

The analyses presented by Subcommittee Two are based on two instances of State law that require the collection and testing of an individual's DNA. First, the subcommittee considered Chapter 70.83 RCW and Chapter 246-560 WAC concerning the State's Newborn Screening Program. State law (Chapter 70.83 RCW) requires "… screening tests of all newborn infants before they are discharged from the hospital for the detection of phenylketonuria and other heritable or metabolic disorders [such as congenital hypothyroidism, congenital adrenal hyperplasia, and hemoglobinopathies] leading to mental retardation or physical defects as defined by the state board of health: PROVIDED, That no such tests shall be given to any newborn infant whose parents or guardian object thereto on the grounds that such tests conflict with their religious tenets and practices." SBOH regulations (Chapter 246-650 WAC) adopted pursuant to this statute direct hospitals to obtain blood specimens from infants and send them to the State Public Health Laboratory for testing. The specimens consist of a few drops of blood that are absorbed and dried onto a filter paper form.

The second instance concerns the collection of DNA from felons and certain other criminals and the maintenance of the information gleaned from the sample in a database. The recently amended state law titled DNA Data Base (Chapter 43.43 RCW), requires that "Every

adult or juvenile individual convicted of a felony, stalking … harassment … or communicating with a minor for immoral purposes … must have a biological sample collected for purposes of DNA identification analysis …". These samples are tested according to certain specifications outlined in federal law and are retained by the Forensic Services Bureau of the Washington State Patrol. The statute restricts uses to "… identification analysis and prosecution of a criminal offense or for the identification of human remains or missing persons" or "… improving the operation of the [DNA identification] system." The statute also allows the State Patrol to submit DNA test results to the Federal Bureau of Investigation (FBI) combined DNA index system (CODIS) which is authorized under the DNA Identification Act of 1994 (42 U.S.C.A§14132).

Subcommittee Three: The use of genetic information for research purposes

(note: *a background section was not included with this subcommittee report, if the subcommittee wishes to provide one and replace the following text, please draft text for the GTF to review at the Sept 4th meeting*) Subcommittee Three examined the collection and use of genetic information for research purposes. This subcommittee considered the many variations of research and whether genetic information obtained in the course of research can be considered different from genetic information obtained in the course of health or medical care. For example, DNA testing conducted under a research protocol may not have clinical significance and furthermore, the testing may not have been conducted in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory. If this is the case, test results are generally not communicated to research participants nor included in the individual's medical chart. However, some DNA test results obtained under a research protocol are communicated to research subjects

either verbally or in writing. Once a test result is communicated to an individual, it becomes part of his or her personal health information. One of the questions faced by this subcommittee concerned whether DNA test results obtained under a research protocol were afforded the same protections as DNA test results obtained through routine medical care.

Subcommittee Four: The use of genetic information for social purposes such as health, life and disability insurance and employment

(note: *a background section was not included with this subcommittee report, if the subcommittee wishes to provide one and replace the following text, please draft text for the GTF to review at the Sept 4th meeting*) Other uses of genetic information fell to the consideration of Subcommittee Four. The members of this subcommittee evaluated the potential for employers and insurance companies to use an individual's genetic information. Issues considered by this subcommittee included whether employers could obtain and use genetic information to make employment decisions and what constitutes appropriate use of genetic information in life, health and disability insurance.

Findings

Each subcommittee report outlined findings, conclusions and recommendations from each of these perspectives. The GTF adopted the following findings from the subcommittee reports.

Incidence of discriminatory actions based upon genetic information in Washington State

The GTF heard from the Washington State Human Rights Commission (WSHRC), the Office of the Insurance Commissioner (OIC) and the DOH Genetic Services Section (GSS) regarding evidence of discriminatory actions based upon the use of genetic information. Representatives from WSHRC and the OIC testified that neither agency has cataloged reports or complaints from citizens of Washington State with respect to adverse discriminatory actions resulting from an employer's or insurance company's knowledge of an individual's genetic information. A representative from the DOH GSS provided a log of 38 inquiries and complaints received between November 20, 1991 and November 16, 2001. The Task Force found that three of these incidents represented cases in which family history or genetic status may have been used to adversely discriminate against an individual. The rest of the complaints were based on the need for additional education and/or resources. (Should there be a table or appendix with examples of these complaints?)

The GTF found no additional documented cases of adverse discriminatory actions based upon genetic information obtained or used for diagnostic genetic testing, reproductive decision-making, predictive genetic testing, newborn screening, criminal DNA databases, or research. However, members agreed that the possibility of discrimination based on predictive genetic testing exists. With regard to the use of DNA technology for prenatal or preconception testing, the Task Force found that there is little, if any, risk of discrimination because testing is always voluntary, done with informed consent and test results are maintained within the patient's private medical record. In this same regard, Task Force members reaffirmed the right of individuals to

seek genetic counseling and appropriate genetic testing when they are at risk for transmitting a serious genetic disorder and the rights of children born with genetic conditions to be free from discrimination because of any immediate or future disability.

Other findings of the Task Force related to the incidence of discriminatory actions based upon genetic information were based on a review of the legislation, policies, and procedures associated with the Newborn Screening Program, the State's Criminal DNA Database, research activities, insurance practices, and employment practices.

The GTF found that no active surveillance systems are in place to proactively monitor the use of genetic information created and stored within the scope of the Newborn Screening Program or the Criminal DNA Database. There are formal reporting systems that allow research subjects to report perceived abuses that occur during the course of a research study to the Principal Investigator, IRB, or a federal oversight agency such as the National Institutes of Health (NIH) or the Food and Drug Administration (FDA); however, research that is not regulated by federal human subjects standards such as 45 CFR 46 (the Common Rule) and 21 CFR 50 may not have such reporting systems in place. The majority of the Task Force found that information from DNA studies regarding predispositions to disease might be disclosed to research subjects, but individuals may be protected from some forms of misuse of this information by Washington Administrative Code, which prohibits health plans (defined in Chapter 48.43.005(19) RCW) offered by health carriers from treating genetic information as a health condition in the absence of a diagnosis of the condition related to such information.

With respect to the incidence of discrimination based upon genetic information used for social purposes such as insurance and employment, the Task Force found that State agencies do not systematically survey people or make proactive efforts to collect information regarding

discrimination based on genetic information; however agencies such as DOH, OIC, and WSHRC have passive reporting systems in place for receiving complaints. In addition, the Task Force examined the potential risks of adverse discrimination based upon genetic information in insurance and employment. This examination revealed that statistical tables used by life insurance companies inherently contain factors that may be considered 'genetic information' under some definitions of the term. For example, information about an individual's family history is a common and allowable request for some types of insurance coverage and broader definitions of genetic information may include family history. The GTF also found that health, life, and disability insurers view genetic information as a category of health care/medical information and that some State laws and industry practice disallow the use of health information (including genetic information) to set rates for, cancel, or not renew a consumer of health insurance; in particular, RCW 48.18.480 prohibits unfair discrimination in insurance matters and WAC 284.43.720 states that "health carriers may not reject a health plan applicants and may not limit or exclude plan coverage for any reason associated with health risk or perceived health risk except for the imposition of a preexisting condition exclusion as permitted in this chapter." Furthermore, disability and life insurance may use health information to underwrite a policy but state law and/or industry practice prohibits the use of health information to cancel or not renew an existing consumer of these policies. The following is a summary of some of the laws and policies governing insurance practices in Washington State.

Individual, small, and large group health insurance plans may contain a waiting period of up to 9 months for coverage of preexisting conditions (RCW 48.43.012; RCW 48.43.025 (1); RCW 48.43.025 (2), but genetic information cannot be considered a health condition unless it is accompanied by a diagnosis of the condition (WAC 284-43-720(3)).

When a diagnosis of a health condition accompanies genetic information, Washington State law limits the use of pre-existing conditions to exclude individuals from different types of insurance. Pre-existing condition limitations vary for long-term care, Medicare supplemental, individual or group disability insurance. Depending on the plan, the use of genetic information to define a preexisting condition may not be prohibited by law for long-term care, Medicare supplemental, individual or group disability insurance plans.

In general, life insurance companies can use health care information, including genetic information, to deny coverage or to set initial rates; there are no laws preventing the use of preexisting conditions in life insurance underwriting. However, regulations do prohibit cancellation of a policy because of health conditions that emerge after issuance. Life insurance rates are term-based and policies may be periodically re-classified.

Property and casualty insurance plans generally do not consider health care information when enrolling clients, however the use of health care information for these plans is not specifically prohibited. An insurer using health care information to deny, cancel or set rates must justify the action.

Regarding the risk of adverse discrimination in employment based on genetic information, the majority of the GTF found that existing state and federal laws such as the WLAD (Chapter 49.60 RCW) and the ADA may be applicable in cases of employment or other discrimination based on genetic information. However, the scope and interpretation of these laws with respect to genetic information has not been challenged in the courts.

WLAD prohibits employers from refusing to hire, discharging or barring, or discriminating against any person in compensation based on any sensory, mental, or physical handicap. The WSHRC writes rules and oversees the implementation of the WLAD. A

representative from WSHRC testified to the GTF that WSHRC rules are broad enough to allow the agency to investigate and take action against claims of discrimination based upon genetic information if they arise. The scope of the WLAD also includes circumstances surrounding real estate, public accommodation, credit, and insurance practices.

The ADA states that before making an offer of employment, an employer may not ask job applicants about the existence, nature, or severity of a disability; applicants may be asked about their ability to perform job functions. Under the ADA, a job offer may be conditioned on the results of a medical examination, but only if the examination is required for all entering employees in the same job category and the medical examination is job-related and consistent with business necessity. The Equal Employment Opportunities Commission (EEOC) writes rules pertaining to and oversees the implementation of the ADA. The EEOC rules address the retention, storage and use of employees' health information. The EEOC considers the scope of the ADA to include genetic tests and genetic information and believes that employers who discriminate against employees on the basis of predictive genetic tests "regard" the employees as having a disabling impairment and are therefore acting in violation of the ADA (insert reference: 2EEOC Compliance Manual, secs. 902-45, March 14, 1995). Neither the WSHRC interpretation of the WLAD or the EEOC interpretation of the ADA with respect to the applicability of these statutes to cases involving discrimination based upon genetic information have been tested in court.

Additional legislation regarding protection from discrimination in employment includes Chapter 49.44.010 RCW, which prohibits "blacklisting" by employers. This statute prohibits an employer from willfully or maliciously making a statement with the intention of preventing a person from securing employment.

A minority of the GTF disagreed with the above finding that existing laws provide substantive protection against discrimination based on genetic information. Mr. Ty Thorsen and Professor Philip Bereano questioned the scope and applicability of existing legislation to protect against a significant risk of discrimination based on genetic information. Mr. Thorsen and Professor Bereano noted that protections provided by privacy regulations such as HIPPA and the Uniform Health Care Information Act may be insufficient to prevent access to and therefore the misuse of genetic information by employers or insurers. Furthermore, they found that the recent Supreme Court decisions suggest a more narrow scope and interpretation of the ADA. (are there specific cases that we can reference?)

Overall, the Task Force agreed that receiving very few reported cases of adverse discriminatory actions based upon genetic information does not prove that such incidents do not occur more frequently, rather this finding is an indication that such incidents are not reported to or actively observed by State agencies. The GTF could not conclude, from the information provided to it, the underlying reason(s) for the lack of reported discriminatory actions based upon genetic information. However, the GTF found that the lack of reported cases does not indicate that there is no risk of adverse discrimination based upon genetic information.

Strategies to safeguard civil rights and privacy related to genetic information

The GTF received information about several state and federal strategies that may protect individuals' civil rights and privacy with respect to their genetic information. Strategies at the state level include the Uniform Health Care Information Act (RCW 70.02), the Patient's Bill of Rights (SB 6199), Release of Records for Research (Chapter 42.48 RCW), the Governor's

Executive Order on Privacy (EO 00-03), and various legislation including WAC 284.04.500, WAC 246.320.205 (2) (5), RCW 43.105.310, and RCW 51.28.070 that regulate the privacy of health care information held by health insurers, hospitals and state agencies. Federal laws, regulations and policies include the HIPAA Privacy Rules, the ADA and EEOC rules, and the Protection of Human Subjects (45 CFR 46 and 21 CFR 50) regulations. The Task Force found that these existing laws, regulations and policies provide substantive protection with respect to an individual's privacy and civil rights relating to his or her genetic information. However, the GTF identified some ambiguities and/or weaknesses in existing legislation and a minority of the GTF noted specific gaps and/or lack of protection against certain privacy or civil rights violations.

Specifically, the majority of the Task Force found that state and federal laws protect the privacy of medical records. Notably, the State Legislature recently amended the definition of "health care information" in the Uniform Health Care Information Act (Chapter 70.02 RCW) by passing ESSB 5207 in March 2002. The statutory definition of "health care information" now includes DNA.

The GTF received evidence that indicated that newborn blood spots obtained and used in the Newborn Screening Program and the data associated with these spots fit within the definition of health care information and fall under the purview of this state law. To the extent that genetic information generated in the course of research is considered health care information, the Uniform Health Care Information Act also protects the privacy of this information. GTF members noted, however, that there is a question as to whether some research data is considered health care information. The Uniform Health Care Information Act also prohibits the unauthorized disclosure of identifiable health care information by a health care provider for

research purposes unless such disclosure meets IRB approval (70.02.050 1(g)). The Uniform Health Care Information Act does not protect the privacy of health care information, including genetic information, held outside of the health care system.

Other state laws address the privacy and civil rights of research subjects and individuals seeking or holding an insurance policy. For example, the Release of Records for Research statute (Chapter 42-48 RCW) provides parameters under which a state agency may disclose individually identifiable personal information for research purposes and under which researchers may further disclose such information. Additionally, the Patient's Bill of Rights (SB 6199) and WAC 284-04-500 mandate that health carriers and insurers adopt policies and procedures that conform administrative, business, and operational practices to protect an enrollee's right to privacy or right to confidential health care services granted under state or federal laws. Another strategy adopted by the State is the Governor's Executive Order on Privacy (EO 00-03), which protects the privacy of all readily identifiable personal information held by a state agency or contractor. EO 00-03 prohibits state agencies, employees or contractors from disclosing identifiable personal information to any party without legal authority. Finally, various pieces of legislation such as WAC 246.320.205 (2) (5), RCW 43.105.310, and RCW 51.28.070 mandate that hospitals and state agencies such as the Department of Labor and Industry maintain specific standards of privacy.

In addition to protections afforded to health information, a majority of the Task Force noted that existing safeguards adequately protect the privacy of genetic information collected and stored as part of the criminal DNA database system. Uses for this information are restricted in both state and federal law. Furthermore, the segments of DNA tested in this program are not associated with any known medical condition or disease. Professor Bereano disagreed with the

finding that existing safeguards adequately protect genetic information collected for and stored within the criminal DNA database system.

The Task Force found that some federal laws also provide protection for an individual's privacy and civil rights with respect to their genetic information. The HIPAA Privacy Rules, to which covered entities must comply by April 2003, apply to health plans, health care clearinghouses, and those health care providers who conduct certain financial and administrative transactions electronically. Health care information is defined within HIPAA as "any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse and relates to the past, present or future physical or mental health or condition of an individual or the provisions of health care to an individual or the past, present, or future payment for the provision of health care to an individual." A report published by the National Conference of State Legislatures (NCSL) states, "this definition includes currently manifested diseases of genetic origin as well as genetic information, since such information "relates to" a possible future medical condition." (insert reference: NCSL "Genetics Policy and Law: A Report for Policy Makers", September 2001)

The HIPAA Privacy Rules grant patients specific control over the release and use of their health information. A previous version of the Rules required physicians to obtain the consent of patients before releasing private health information for purposes related to health care treatment, payment and health care operations termed "routine uses." Under these rules, providers were not required to provide care if the patient did not consent to the release of information for these purposes (NCSL). However, an August 2002 revision by the Department of Health and Human Services (HHS) changed this rule. Under the new rule, a patient's consent is no longer required

for the release of health information for the purposes of treating patients, paying bills and carrying out various "health care operations." Disclosures for other purposes require patient authorization but a physician cannot deny a patient care in the absence of such authorization (NCSL). With respect to research, the new HIPAA Privacy Rules allow researchers to use a single combined form to obtain informed consent for the research and authorization to use or disclose protected health information for such research. The new Rules also specify requirements relating to a researcher obtaining an IRB waiver of authorization by streamlining waiver criteria to more closely follow the requirement of the "Common Rule," (45 CFR 46) which governs federally funded research.

HIPAA does not apply to individual or small group (defined as less than 50 individuals) health plans and the regulations do not apply to entities outside of the health care system. Furthermore, there is no active surveillance or monitoring system that ensures compliance with these regulations. More restrictive state laws preempt the HIPAA Privacy Rules and separate privacy mandates exist at both the state and national level that protect information held by the criminal justice system, schools, public health agencies, mental health providers, and other entities.

Other federal laws such as the ADA, 45 CFR 46 and 21 CFR 50/56 aim to protect individuals from unauthorized disclosure or use of their health information by employers and researchers. The ADA and rules adopted by the EEOC define the type of information an employer can request and use in making employment decisions.

Federal regulations such as 45 CFR 46 and 21 CFR 50/56 regulate the conduct of research involving human subjects. 45 CFR 46 applies to “all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency

which takes appropriate administrative action to make the policy applicable to such research…It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States." The regulation also states that "research that is neither conducted nor supported by a federal department or agency, but is subject to regulation as defined in Sec 46.102(e) must be reviewed and approved, in compliance with Sections 46.101, 46.102, and 46.107 through Section 46.117 of [the] policy, by an institutional review board that operates in accordance with the pertinent requirements of [the] policy." (45 CFR 46 Sec 46.101 (a) and Sec 46.101 (a)(2)). In addition, some private funding sources may require that researchers comply with 45 CFR 46. Still other privately funded researchers may voluntarily abide by 45 CFR 46 regardless of their funding or regulatory source.

Research regulated by the Food and Drug Administration (FDA) is subject to the purview of 21 CFR 50 and 21 CFR 56, which specify requirements for the protection of human subjects in research and the circumstances under which IRB review is required. Researchers and IRBs are subject to routine inspections to verify compliance with these federal regulations; they also have extensive reporting responsibilities to parent agencies. In addition, researchers, IRBs and federal oversight agencies accept and investigate complaints from research subjects regarding violations of these regulations. Evidence presented to the GTF showed that complaints to research oversight agencies reached an all time high in 2002.

According to these regulations, different research study designs require different levels of informed consent. For example, research using "anonymized" biological samples from which all information that could identify the individual from whom they were obtained has been removed may not require the informed consent of the individuals from whom the samples were obtained. However, research that involves samples linked to information from which the donor can be

identified almost always requires the consent of the individual who originally provided the information or biological sample. The Task Force noted that genetic research activities conducted without federal financial support, in facilities that have not voluntarily adopted the federal protections, and that do not involve FDA-regulated test articles are not required to conform to and follow legal requirements and standards established for the involvement of human subjects in research.

Certificates of confidentiality constitute another level of protection available to research subjects. Researchers may apply for a federal certificate of confidentiality to protect research data from court-ordered disclosures under most circumstances.

A minority of the Task Force consisting of Mr. Ty Thorsen, Dr. Wylie Burke, and Ms. Robin Bennett found that Washington's law on domestic relations (RCW 26.04.020), which prohibits marriage "when the husband and wife are nearer of kin to each other than second cousins…," may violate privacy and civil rights. This finding is based on evidence indicating that the genetic risk for progeny of first cousin marriages is only minimally increased above population risk (insert reference: "Genetic counseling and screening of consanguineous couples and their offspring: recommendations of the National Society of Genetic Counselors." Journal of Genetic Counseling 11(2) April 2002, 97-119). Thus, the level of risk in this circumstance is not great enough to justify the violation of an individual's right to privacy and civil rights with respect to marriage.

In summary, the Task Force received information about existing state and federal laws, regulations, and policies that may apply to an individual's privacy and civil rights with respect to genetic information. Based on this information, the majority of the Task Force found that at present the scope and interpretation of existing laws provide substantive protection of an

individual's privacy and civil rights regarding genetic information. The Task Force noted, however, that the extent to which these laws encompass genetic information varies, and in some situations may be poorly defined and untested. Furthermore, the scope and interpretation of some of these laws may change over time and with increasing demands on the legal system to apply these laws to situations in which the central issue is the use or disclosure of genetic information. A minority of the Task Force disagreed with this finding and noted that gaps and ambiguities in existing laws leave open the opportunity for privacy and civil rights violations to occur. Specific conclusions and recommendations commensurate with these findings are discussed later in this report.

Remedies to compensate individuals for inappropriate use of genetic information

The Task Force found that avenues for obtaining compensation or punishing violators exist within the current legal tort system. Many of the strategies reviewed in the previous section include clauses pertaining to compensation or legal action in cases where inappropriate use of genetic information occurs. In most circumstances, claims of privacy or civil rights violations must be reported to an oversight agency and/or brought before a court of law. Specifically, the Task Force found that the Washington State OIC has the authority to investigate claims and levy fines against violators and the following laws contain provisions that may allow for compensation for victims and/or legal action against those who inappropriately use genetic information.

- The Uniform Health Care Information Act provides that action can be brought against a "…health care provider or facility who has not complied with this

chapter." Relief is limited to actual damages and attorney fees and other expenses of bringing the action. The individual must state the claim within two years after the cause of action is discovered.

- The Release of Records for Research statute (Chapter 42.48.050 RCW) states that any unauthorized disclosure of personally identifiable information by a researcher who obtained the information from a state agency is a gross misdemeanor subject to fines up to $10,000 for each violation.
- The WLAD does not provide for specific compensation, however, the WSHRC receives and investigates complaints and may hold hearings and subpoena witnesses. If WSHRC efforts fail to remedy the problem, the matter may be sent to the Attorney General for litigation before the Administrative Law Judge. In addition, individuals may sue for discrimination under this statute.
- The Patient's Bill of Rights permits individuals to sue violators and allows the parties involved to request an independent review process.
- The Health and Human Services Office for Civil Rights (OCR) enforces the HIPAA Privacy Rules. OCR relies on reports and formal complaints regarding violations and will investigate claims of violations and seek 'informal' resolutions of noncompliance. If an informal resolution cannot be achieved, OCR may apply civil monetary fines or work with the Justice Department to seek criminal prosecution. Civil monetary penalties are $100 per violation and capped at $25,000 per year. Criminal fines range from $50,000 - $250,000 and prison terms range from 1 to 10 years.

- The EEOC is the regulatory body for the ADA. The EEOC relies on individuals to report violations, as there is no active monitoring system. Reported violations are investigated and in cases of wrongdoing, the EEOC may sue violators in court. Individuals may also file suit against those in violation of the ADA. Professor Bereano noted that it is unlikely that employees would be aware of the misuse of their genetic information and therefore unlikely to report violations.
- The Protection of Human Subjects regulations (45 CFR 46 and 21 CFR 50) require IRBs to monitor compliance with federal and local regulations. Federal oversight agencies may also conduct periodic inspections. IRBs rely on internal and external reviews and inspections of research proposals and reporting of violations by research subjects or others. The FDA inspects entities regulated by the FDA for compliance with FDA regulations. Penalties include fines, suspension of research activities and suspension of federal funding for research involving humans. In addition, victims of violations may sue researchers and institutions that house research.
- The federal DNA Identification Act (1994) establishes criminal penalties for individuals who knowingly violate privacy protection standards and provides that access to the federal system is subject to cancellation if privacy requirements are not met. The Act does not provide individuals with specific remedies for the inappropriate use of their genetic information.

Task Force members found that legal avenues available to individuals who are victims of the misuse of their genetic information consist of reporting violations to administrative and/or

oversight agencies and pursuing actions against perpetrators in court. Most of the laws reviewed by the GTF that are aimed at protecting an individual's civil rights and privacy provide for civil and/or criminal penalties in cases of wrongdoing.

Incentives for further research and development in the use of DNA to promote public health, safety and welfare

Representatives from academic/basic science research, public health, and the biotechnology industry appeared before the GTF to discuss issues related to genetic research in Washington State. Expert panelists representing each of these three types of research discussed the current and future contributions of genetic research to public health, safety and welfare and the regulations, practices, and methods pertaining to different types of genetic research.

The panelists informed the Task Force that the potential benefits of genetic research and emerging genetic technology include: achieving a better understanding of many aspects of human biology; the development of tools for medical care including, disease prevention, diagnosis, and treatment; expansion of genetic testing as an aid for the reproductive health of mothers and fetuses; and the development of genetic tests that will identify individuals at risk for developing adult onset diseases for which interventions may be available such as diabetes, hypertension, renal disease, and cardiovascular disease. Previous and ongoing research has resulted in the development of numerous genetic tests. However, the full benefits and clinical applicability of some of these tests may not yet be realized because knowledge about the significance of test results with respect to outcomes and other consequences is lacking for many of these tests. Ongoing and future genetic research such as studies aimed at associating

genotypes with phenotypic profiles may be important to medical and public health knowledge in this area as well as to the development of screening programs, education and intervention programs, and therapies. The Task Force noted, however, that the issuing of patent for specific DNA sequences may interfere with basic research and the useful development of genetic tests for clinical purposes.

Access to research subjects and biological material is important for studies investigating the relationship between genotype and phenotype and the continued development of genetic tests, technology and pharmaceuticals. Under current policies, research involving human subjects may be subject to different oversight requirements depending on the source of funding and/or regulation or level of anonymity involved in the data collection process. For some study designs, anonymous research samples, for which informed consent may not be required, are adequate. Other studies require the use of identifiers to match clinical data with genotype data. The latter type of research most often requires informed consent from, and therefore access to, the individuals from whom the samples and clinical data were derived. Several presenters noted that fear of discrimination is a reason that people may choose not to participate in genetic studies.

Regarding incentives for further research and development in the use of DNA to promote public health, safety and welfare, representatives from the biotechnology industry commented that their research and business endeavors are sensitive to changes in policy that may affect their ability to conduct research. The Task Force found from other testimony that academic/basic science, public health and biotechnology researchers receive adequate incentives to conduct genetic research. Incentives exist within the medical community for researching and developing uses of DNA to promote predictive testing of late onset diseases. For example, there is funding

available for and ongoing research on predicting individuals at risk for developing diabetes, hypertension, renal disease, and cardiovascular disease. In addition, government and private funds exist to expand the use of genetic testing in reproductive medicine. Incentives at the state level include the availability of newborn screening specimens for research as long as appropriate safeguards are followed. However, the state does not allow the use of samples or data from the criminal DNA database for research beyond that which may "…improve the operation of the system…" and federal law permits the use of these samples and data only if personal identifiable information is removed for "…a population statistics database, for identification research and protocol development purposes, or for quality control purposes."

The presentations given by the research representatives to the GTF revealed that there are many potential benefits of genetic research and development and that research involving human subjects is regulated at several levels. However, different regulations apply to different types of research and adherence to specific regulations depends on funding sources, regulatory/oversight agencies, and research study designs. The Task Force found that incentives to continue genetic research and development exist in the form of funding and opportunities created by industry, academic and government research agendas.